K022968

510(k) Summary of Safety and Effectiveness

SEP 2 4 2002

The following information provides data supporting a substantially equivalent determination for the ADVIA TESTpoint CSF Controls.

Predicate Device
Cell-Chex body fluid controls manufactured by Streck Laboratories, Inc (K000076).

Intended Use
ADVIA TESTpoint CSF Controls are hematology reference materials for monitoring the precision and accuracy of the ADVIA 120 Hematology System when analyzing CSF samples.

Device Description
ADVIA TESTpoint CSF Controls is an assay control mixture used for quality control of the ADVIA 120 CSF (cerebral spinal fluid) method. The control materials are composed of red blood cells and white blood cells derived from human sources stored in a stabilizing medium. The control materials consist of two levels that simulate a low cell count (Level 1) and a higher abnormal count (Level 2).

The following RBC and WBC parameters are reportable with the control materials:

Level 1
WBC - white blood cell count
RBC – red blood cell count

Level 2
WBC - white blood cell count
RBC – red blood cell count
% Neut – percent neutrophil count
% Lymph – percent lymphocyte count
% Mono – percent monocyte count
% Eos – percent eosinophil count
% MN – percent mononuclear cell count
% PMN – percent polymorphonuclear cell count

Comparison with Predicate Device
The following table provides similarities and differences between ADVIA TESTpoint CSF Controls and the predicate device (K000076).

Similarities/Differences	Characteristic	Predicate Device	ADVIA TESTpoint CSF Controls
Similarities	Intended Use	Quality control material for control of cerebrospinal fluid cell counts.	Same as predicate device.
	Control Composition	Human red blood cells and human white blood cells in a preservative medium.	Similar to predicate device.
	Targeted Control Ranges	Level 1 – Low cell count Level 2 – High abnormal cell count	Similar to predicate device.
Differences	Intended Use	Intended to control manual cell counts.	Intended to control ADVIA 120 automated cell counts.
	Level 1 WBC Differential	Two part WBC Differential	No WBC Differential on Level 1
	Level 2 WBC Differential	Two part WBC Differential	Five part WBC Differential

Conclusion

The test results included in this submission demonstrate that the ADVIA TESTpoint CSF Controls are substantially equivalent to the predicate device. The control materials have demonstrated acceptable precision as observed by the minimal variability (SD and %CV) found in stability testing, and meets the manufacturer's intended specifications for both shelf life and open vial stability.

Date 9/05/02

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Corporation
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 4 2002

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511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k022968
Trade/Device Name: ADVIA TESTpoint CSF Controls
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: Class II
Product Code: JPK
Dated: September 6, 2002
Received: September 6, 2002

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K022968

Device Name: ADVIA TESTpoint CSF Controls

Indications for Use: ADVIA TESTpoint CSF Controls are hematology reference materials for monitoring the precision and accuracy of the ADVIA 120 Hematology System when analyzing CSF samples.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices K022968
510(k) Number